

Study Report

The Determination of Selected Analytes in Aerosol

Prepared for:

**Vapepal
The Old Brewery Business Centre
Castle Eden
County Durham
United Kingdom**

Report Issued: 13 April 2018



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Appendix A – CARBONYLS AEROSOL Results

I. STUDY OVERVIEW

The objective of this study was to determine the concentration of selected analytes in aerosol.

The client provided eleven brands, which are listed in Table I. One replicate per brand were determined to be used for testing.

The analysis requested for this study is listed in Table II.

The laboratory control type used for acceptance was included on each final table for a given test method.

No deviation occurred during the course of this study.

The analytical method summary and results are included in the attached appendix.

These reported results were electronically submitted to the client on 13 April 2018.

II. TESTING FACILITY

Activities were conducted at:
Enthalpy Analytical, LLC
1470 East Parham Road
Richmond, VA. 23228-2300

III. TEST SAMPLES

A. Receipt, storage and conditioning of test samples

- Samples were received on 13 April 2018.
- The brand code designations are given in Table I.
- Storage was maintained at ambient conditions (unless otherwise specified by the client) until testing was required.
- Samples for testing were handled according to SOP LAB-013 Sample Handling (General).

Table I. Brand Coding and Sampling

Client Sample ID	Enthalpy Sample ID	Quantity Received
Fc Virginia Tobacco 18mg	A	1
SC Oriental Tobacco 18mg	B	1
Menthol 18mg	C	1
Mint 18mg	D	1
Strawberry 18mg	E	1
Blueberry 18mg	F	1
Banana 18mg	G	1
Cherry 18mg	H	1
Mango 18mg	I	1
Watermelon 18mg	J	1
Vanilla 18mg	K	1

B. Constituents List

All applicable analytical methods have been fully validated (unless otherwise specified). For lists of specific compounds of interest identified in each analyte group to be reported, refer to the appendices.

Table II. Constituents List

Analyses	Analytical Method Reference #	Validation Report #
Carbonyls in E-Cigarette Aerosols by HPLC	AM-236 V 3.0	VR-236

C. Sample Generation and Records

All analytical results generated in this report were conducted per client specific (or protocol, if available) parameters and conditions.

Records will be stored by Enthalpy for a period of ten years. Following this period, all records will be destroyed. Electronic records are maintained indefinitely.

Calibration curve and sample chromatograms are available upon request.

IV. QUALITY STATEMENT\SIGNATURES

I certify to the best of my knowledge, all analytical data presented in this report summary:

- Has been reviewed for consistency and completeness
- Is accurate, error-free, and legible
- Has been conducted in accordance with ISO/IEC 17025:2005 Standards; In instances where no regulatory guidance exists or is not applicable, the study was conducted in accordance with Enthalpy Analytical quality and technical procedures, and/or approved protocol

Outliers were evaluated, where deemed necessary. If any were discovered and an assignable cause was determined, they were noted and repeats conducted.

This report is considered to describe accurately the procedures used in this study and the results obtained.

QA Reviewed By: _____

General Reporting Notes

Acronym	Name	Explanation
BQL J <LOQ	<i>Below Quantitation Limit</i> <i>J-Flag</i> <i>Less than LOQ</i>	Indicates detection of the analyte, but at a value less than the LOQ. The laboratory can positively identify the presence of the analyte of interest, but it cannot be reliably quantitated.
DF	<i>Dilution Factor</i>	This number represents a dilution of the sample during the preparation and/or analysis process. The analytical result taken from a laboratory instrument is multiplied by the DF to determine the final, undiluted sample result.
E	<i>E-Flag</i>	Indicates an analytical result exceeding the highest calibration point. The associated value should be considered an estimate.
PCS	<i>Process Control Sample</i>	Clean matrix or a reference matrix that is prepared and analyzed using the same reagents, procedures and spiking standards (if applicable) used for the client samples. Used to assess the control of the laboratory's analytical system. Examples: LCS, 3R4F, CM7
LOQ	<i>Limit of Quantitation</i>	(aka: <i>Lowest Standard Value</i> or <i>Lower Curve Limit</i>). The laboratory cannot reliably quantitate analytes of interest below this value within method criteria. The result is considered an estimate.
MDL	<i>Minimum Detection Limit</i>	The laboratory cannot determine the presence of the analyte reliably below this value.
-Mod	<i>Modified</i>	Indicates that the SOP used has been modified to meet the needs of the analysis.
MS	<i>Matrix Spike</i>	An aliquot of an actual sample spiked with a known amount of analyte to determine possible percent recovery. The MS indicates what effect the sample matrix may have on the target analyte.
ND	<i>Non-Detect</i>	Indicates an analytical result below the MDL.

- **Significant Figures:** Where the reported value is much greater than unity (1.00) in the units expressed, the number is rounded to a whole number of units rather than to 3 significant figures. For example, a value of 1,456.45 µg/mL is rounded to 1,456 µg/mL. There are four significant digits displayed, but no confidence should be placed on more than two significant digits.
- **Manual Integration:** The data systems used for processing will flag manually integrated peaks with an "M." Several reasons a peak may be manually integrated (listed below) will be identified by two-letter designations on sample chromatograms, if provided in the report. These codes will accompany the analyst's manual integration stamp placed next to the compound name on the chromatogram.
 - **NI:** The peak was *not integrated* by the software
 - **II:** The peak was *integrated incorrectly* by the software
 - **WP:** The *wrong peak* was integrated by the software

APPENDIX A

CARBONYLS AEROSOL RESULTS

The results in this test report relate only to the samples identified in this report. This information is confidential and is only to be used by the client identified in this report. Enthalpy Analytical, LLC accepts no liability in the use of this report or the results contained, herein. The original controlled report shall not be reproduced without written approval of Enthalpy Analytical, LLC.

SELECTED CARBONYLS IN E-CIGARETTE AEROSOL BY HPLC-UV

ENTHALPY ANALYTICAL METHOD AM-236: VALIDATION REPORT VR-236

Diacetyl, Acetyl propionyl (aka 2,3-pentanedione), Formaldehyde, Acetaldehyde, Acrolein, and Crotonaldehyde data was generated by Enthalpy Analytical (Richmond, VA), LLC in accordance with Enthalpy SOP AM-236. E-Cigarettes are vaped using an analytical vaping machine. The vapor is collected on a 44-mm Cambridge filter pad (CFP) and in an impinger containing DNPH derivatizing reagent. The Cambridge pad is discarded. The derivatization solution generates a colored adduct that can be analyzed by HPLC-UV.

Enthalpy Analytical

0318-009 (Q18080) AM-236 Carbonyls Aerosol

Vapepal

Analyst: A. Wilson

QA Approved By: R. Norton

Summary

Client Sample ID	Enthalpy Sample ID	Run	Port	Cigs	Puffs /Cig	Acetaldehyde ug/puff	Acrolein ug/puff	Formaldehyde ug/puff
Fc Virginia Tobacco 18mg	0318-009C-A-R1-1	1	5	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
SC Oriental Tobacco 18mg	0318-009C-B-R1-1	1	6	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Menthol 18mg	0318-009C-C-R1-1	1	7	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Mint 18mg	0318-009C-D-R1-1	1	8	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Strawberry 18mg	0318-009C-E-R1-1	1	9	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Blueberry 18mg	0318-009C-F-R1-1	1	10	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Banana 18mg	0318-009C-G-R1-1	1	11	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Cherry 18mg	0318-009C-H-R1-1	1	12	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Mango 18mg	0318-009C-I-R1-1	1	13	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Watermelon 18mg	0318-009C-J-R1-1	1	14	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Vanilla 18mg	0318-009C-K-R1-1	1	15	1	20.0	ND (<0.0614)	ND (<0.0613)	ND (<0.0618)
				Count	1	1	1	1
Laboratory Control (expressed as %)	0318-009-RECOVERY-01	1			NA	NA	NA	95.4

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